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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

HM12/1106

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ART UNIT

PAPER NUMBER

1651

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/806,558

Applicant(s)
Spiess

Examiner
Christopher Tate

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 30, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other:

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DETAILED ACTION

Claims 15-34 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-34 are rendered vague and indefinite for the following reasons:

- In claims 15 and 27, the metes and bounds with respect to the form of the recited herbal components are not clearly delineated - e.g., are the recited herbal components defining extracts thereof, fractionated extracts thereof, the whole plants, pulverized dried plant material from a particular part thereof (such as the *Vitex agnus-castus* berry), or something else?
- Claim 15 is also unclear by the phrase "with at least one other plant component". Is this intended to define --in combination with at least one other plant component-- or something else?
- Claim 16 recites the limitation "the pharmaceutically active ingredients" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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- Claim 17 is rendered indefinite by the phrase "wherein the preparation is in the form of an extract, powder, ...". It is unclear if one or some or all of the recited plant components would be in extract form, powdered form, and/or the other recited forms within the claimed preparation.

- In claim 23, the phrase "wherein *Tanacetum parthenium* in the form of the plant component and/or a preparation" is completely unclear, especially since this phrase implies that *Tanacetum parthenium* is also defining the other plant component and not just itself. Further, it is unclear as to what "preparation" is being defined by "a preparation" within this phrase - e.g., is it --the preparation-- of claim 15 or some other preparation.

- Claims 24-26 are unclear for the same reasoning above with respect to the phrase "the plant component and/or a preparation".

- Claims 23, 25, 26, 30, 32, and 33 are rendered vague and indefinite by the phrase "preferably".

A broad range or limitation followed by linking terms (for example, preferably, maybe, for instance, especially) and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired (see MPEP 2173.05(C) for additional information).

- Claim 27 is rendered indefinite by the ambiguous and omnibus-type phrase "administering to such a subject" - e.g., is it being administered to a subject in need thereof or not. It is suggested that this phrase be amended to recite --administering to said subject--.

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- Claim 27 is also unclear by the phrase "an effective amount of herbal components and/or a preparation" (lines 2-3) because it is unclear as to how these two differ from each other - i.e., this phrase appears redundant. It is, therefore, suggested that "herbal components and/or" be omitted from this phrase. Claim 34 should also be amended accordingly.
- Claim 28 is unclear by the phrase "of menstrual complaints or of additional gastrointestinal complaints" (lines 2-3) - e.g., it is unclear if the gastrointestinal complaints are associated with the menstrual complaints or if they are in addition to something else.
- Claim 29 is rendered indefinite by the phrase "wherein the preparation as selected from the group ...". It appears the word "as" therein should instead be --is--.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17, 21, 22, 27, 29, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazarowych et al. (WO 96/22774) or by the Product Alert Bulletin regarding Alvita Herbal RemeTeas (22 July 1996 - PROMT Abstract).

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An herbal pharmaceutical preparation comprising *Tanacetum parthenium* (feverfew) and at least one other plant component such as *Zingiber officinale* (ginger) is claimed. Also claimed is a method of treating or preventing a migraine in such a subject by administering the herbal preparation to a subject in need thereof.

Lazarowych et al. teach the treatment of migraines using an herbal composition comprising *Tanacetum parthenium* and which may also contain ginger for such purpose. (see, e.g., pages 1-6).

The Product Alert Bulletin discloses a commercial product from Alvita Herbal RemeTeas called Migra-Wonder™ which comprises feverfew and ginger and which, as the name clearly implies, is used to treat headaches including migraine headaches (see abstract).

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 15-17, 21, 22, 23, 26-30, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarowych et al. (WO 96/22774), the Product Alert Bulletin regarding Alvita Herbal RemeTeas (22 July 1996 - PROMT Abstract), Marles et al. (J. Nat. Prod., 1992), and the admitted state of the art.

The Lazarowych et al. and Product Alert Bulletin references are relied upon for the reasons discussed *supra*.

Marles et al. disclose that it is well known in the art that *Tanacetum parthenium* preparations, containing a result-effective content of the active ingredient parthenolide therein, are well known in the herbal art for treating and preventing migraine headaches (see, e.g., pages 1044-1045). Marles et al. also disclose it is well known in the herbal art that *Zingiber officinale* (ginger) is traditionally used for treating and preventing migraines (see, e.g., paragraph bridging pages 1046-1047).

In addition, as readily admitted by applicant, *Tanacetum parthenium* is well known in the herbal art (feverfew) to be useful for treating and preventing migraines (see, e.g., page 4, first full paragraph of the instant specification). Further, as readily admitted by applicant, most migraine sufferers are women and they are most likely to suffer a migraine during their menstrual periods (see, e.g., the last six lines on page 3 of the instant specification).

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine *Tanacetum parthenium* and *Zingiber officinale* for their known benefit in treating and/or preventing migraine headaches (including in a menstruating woman suffering from a migraine), since each is well known in the art for their claimed purpose and for the following reason. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Thus, the invention as a whole is clearly *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wyandt et al. (Drug Topics, June 1998 - PROMT Abstract), Castleman (The Healing Herbs, 1991), Marles et al. (J. Nat. Prod., 1992), the PDR for Herbal Medicines (published Spring 1998), Popp (EP 248215 - DWPI Abstract), and the admitted state of the art, in view of Thys-Jacobs (US 5,443,850).

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Wyandt et al. disclose that feverfew (aka *Tanacetum parthenium*) has a long history of use in traditional and folk medicine as a treatment for menstrual irregularities as well as, more recently, as a treatment for migraine headaches (see abstract).

Castleman teaches that ginger (*Zingiber officinale*) is well known in the art to have traditional use in women's health for treating menstrual cramps and gynecological problems, as well as a digestive aid in relieving gastrointestinal distress (see, e.g., pages 187-188). Marles teaches that ginger is also well known in the art to have traditional use in treating and preventing migraines (see, e.g., paragraph bridging pages 1046-1047).

The PDR for Herbal Medicines reference teaches that *Cimicifuga racemosa* (black cohosh) and *Vitex agnus-castus* (chaste tree) are well known in the art to be useful in treating menstrual/premenstrual disorders (see heading *Indications and Usage* for both plants). In addition, as readily admitted by applicant, it is well known in the herbal art that *Tanacetum parthenium* is useful for treating and preventing migraines (see, e.g., page 4, first full paragraph of the instant specification), and that *Vitex agnus-castus* and *Cimicifuga racemosa* are both useful in treating premenstrual disorders (see, e.g., pages 5-6 of the instant specification). Further, as readily admitted by applicant, most migraine sufferers are women and they are most likely to suffer a migraine during their menstrual periods (see, e.g., the last six lines on page 3 of the instant specification). Also, as disclosed by Thys-Jacobs, seventy percent of women who suffer migraines report a significant proportion of attacks during their premenstrual period (see, e.g., col 1, lines 22-49).

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known beneficial uses since each is well known in the art for such uses (i.e., to treat migraines as well as menstrual/premenstrual disorders, especially since women are the predominant sufferers of migraines and suffer migraines most often during their menstrual/premenstrual periods) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached at (703) 308-4743. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1651 is (703) 308-4242.



Christopher R. Tate
Primary Examiner, Group 1651